(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
18 January 2001 (18.01.2001)

PCT

(10) International Publication Number
WO 01/03642 A1

(51) International Patent Classification[7]: A61J 7/00

(21) International Application Number: PCT/US00/18197

(22) International Filing Date: 30 June 2000 (30.06.2000)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
09/349,715 8 July 1999 (08.07.1999) US

(63) Related by continuation (CON) or continuation-in-part (CIP) to earlier application:
US 09/349,715 (CIP)
Filed on 8 July 1999 (08.07.1999)

(71) Applicant *(for all designated States except US)*: **BRONCUS TECHNOLOGIES, INC.** [US/US]; 1400 N. Shoreline, Bldg. A, Suite 8, Mountain View, CA 94043 (US).

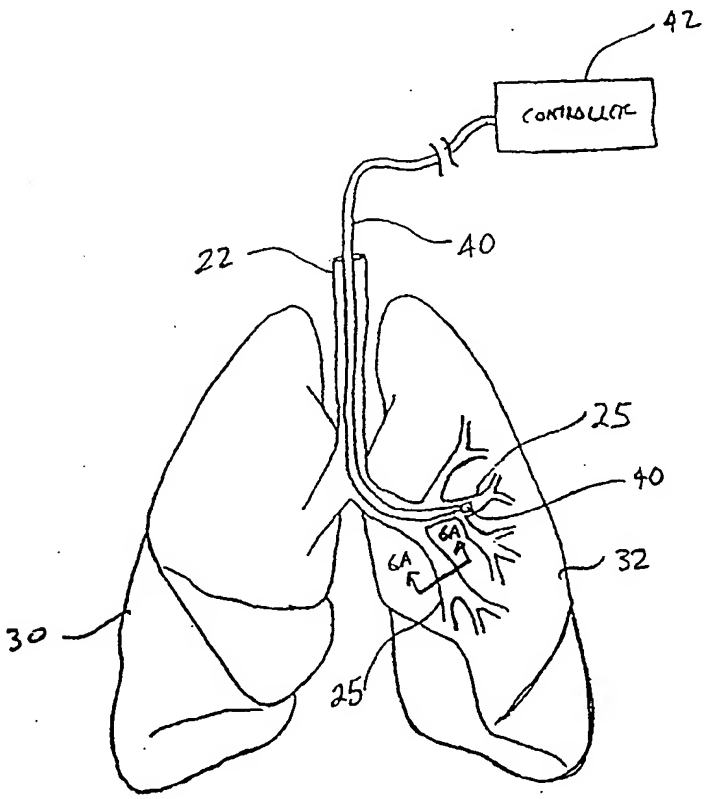
(72) Inventors; and
(75) Inventors/Applicants *(for US only)*: **LAUFER, Michael, D.** [US/US]; 1259 El Camino Real #221, Menlo Park, CA 94025 (US). **THOMPSON, David, P.** [US/US]; 793 Almondwood Way, San Jose, CA 95120 (US). **LOOMAS, Bryan, E.** [US/US]; 17751 McKinnon Drive, Saratoga, CA 95070 (US).

(74) Agents: BAGADE, Sanjay, S. et al.; Morrison & Foerster LLP, 755 Page Mill Road, Palo Alto, CA 94304-1018 (US).

(81) Designated States *(national)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CR, CU, CZ, DE, DK, DM, DZ, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR,

[Continued on next page]

(54) Title: INCREASING GAS EXCHANGE OF A LUNG



(57) Abstract: Methods of increasing gas exchange performed by the lung by damaging lung cells, damaging tissue, causing trauma, and/or destroying airway smooth muscle tone with an apparatus inserted into an airway of the lung. The damaging of lung cells, damaging tissue, causing trauma, and destroying airway smooth muscle tone with the apparatus may be any one of or combinations of the following: heating the airway; cooling the airway; delivering a liquid to the airway; delivering a gas to the airway; puncturing the airway; tearing the airway; cutting the airway; applying ultrasound to the airway; and applying ionizing radiation to the airway.

WO 01/03642 A1

LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW.

(84) **Designated States** *(regional)*: ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

Published:
— *With international search report.*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

INCREASING GAS EXCHANGE OF A LUNG

BACKGROUND OF THE INVENTION

Field of the Invention

The invention relates to a method for treating lung disease, and more particularly, the invention relates to a method of increasing gas exchanging of a lung .

Brief Description of the Related Art

The lungs deliver oxygen to the body and remove carbon dioxide. Healthy lung tissue includes a multitude of air passageways which lead to respiratory bronchiole within the lung. These airways eventually lead to small sacs called alveoli, where the oxygen and carbon dioxide are exchanged through the ultra-thin walls of the alveoli. This occurs deep within the lungs, in an area which is accessed by a network of airways, consisting of a series of branching tubes which become narrower, shorter, and more numerous as they penetrate deeper into the lungs. As shown in FIG. 1, tiny air sacks called alveoli 1 surround both alveolar ducts 2 and respiratory bronchiole 3 throughout the lung. The alveoli 1 are small, polyhedral recesses composed of a fibrillated connective tissue and surrounded by a few involuntary muscular and elastic fibers. These alveoli 1 inflate and deflate with air when we breath. The alveoli are generally grouped together in a tightly packed configuration called an alveolar sac. The thin walls of the alveoli 1 perform gas exchange as we inhale and exhale.

During inhalation; as the diaphragm contracts and the ribs are raised, a vacuum is created in the chest, and air is drawn into the lungs. As the diaphragm relaxes, normal lungs act like a stretched balloon and rebound to the normal relaxed state, forcing air out of the lungs. The elasticity of the lungs is maintained by the supportive structure of the alveoli. This network of connective tissue provides strength to the airway walls, as well as elasticity to the lungs, both of which contribute to the lung's ability to function effectively.

The term "Chronic Obstructive Pulmonary Disease" (COPD) is generally used to describe the disorders of emphysema and chronic bronchitis. Some also consider certain types of asthma to fall under the definition of COPD. Emphysema is characterized by an enlargement of air spaces inside the lung. Chronic bronchitis is characterized by excessive

mucus production in the bronchial tree. Patients with pulmonary disease, such as chronic bronchitis, and emphysema, have reduced lung capacity and efficiency, typically due to the breakdown of lung tissue.

In cases of severe chronic pulmonary disease, such as emphysema, lung tissue is destroyed, reducing the strength of the airways. This reduction in strength of the airway walls allows the walls to become "floppy" thereby losing their ability to remain open during exhalation. In the lungs of an emphysema patient, illustrated in FIG. 2, the walls between adjacent alveoli within the alveolar sac deteriorate. This wall deterioration is accelerated by the chemicals in smoke which affect the production of mucus in the lungs. Although the break down of the walls of the alveoli in the lungs occurs over time even in a healthy patient, this deterioration is greatly accelerated in a smoker causing the smoker's lungs to have multiple large spaces 4 with few connecting walls in the place of the much smaller and more dense alveoli spaces 1 in healthy lung tissue.

A cross section of a diseased emphysematous lung will look like Swiss cheese due to the deterioration of the alveoli walls which leaves large spaces in the tissue. In contrast, healthy lung tissue when seen in cross section has no noticeable holes because of the small size of the alveoli. When many of the walls of the alveoli deteriorate, as shown in FIG. 2, the lung has larger open spaces 4 and a larger overall volume, but has less wall tissue to achieve gas exchange.

In this diseased state, the patient suffers from the inability to get the air out of their lungs due to the collapse of the airways during exhalation. Heavily diseased areas of the lung become overinflated. Within the confines of the chest cavity, this overinflation restricts the in-flow of fresh air and the proper function of healthier tissue, resulting in significant breathlessness. Thus, the emphysema patient must take in a greater volume of air to achieve the same amount of gas exchange. When severe emphysema patients take in as much air as their chest cavity can accommodate, they still have insufficient gas exchange because their chest is full of non-functional air filling large cavities in the lungs. Emphysema patients will often look barrel-chested and their shoulders will elevate as they strain to make room for their overinflated lungs to work.

A wide variety of drugs are available for treating the symptoms, of pulmonary disease, but none are curative. Chronic bronchitis and emphysema are typically treated with antibiotics and bronchodilators. Unfortunately, a large number of patients are not

responsive to these medications or become non-responsive after prolonged periods of treatment.

In severe emphysema cases, lung volume reduction surgery (LVRS) is performed to improve lung efficiency of the patient and allow the patient to regain mobility. In lung volume reduction surgery, a more diseased portion of an emphysematous lung having a large amount of alveolar wall deterioration is surgically removed. LVRS is performed by opening the chest cavity, retracting the ribs, stapling off, and removing the more diseased portion of the lung. This allows the remaining healthier lung tissue to inflate more fully and take greater advantage of the body's ability to inhale and exhale. Because there is more air and more gas exchange in the healthier portion of the lung, lung efficiency is improved.

Lung volume reduction surgery is an extremely invasive procedure requiring the surgical opening of the chest cavity and removal of lung tissue. This surgery has substantial risks of serious post-operative complications, such as pneumothorax, and requires an extended convalescence. The invention described and claimed herein may also be used to treat reversible Chronic Obstructive Pulmonary Disease (COPD), including, but not limited to, such conditions as asthma.

Accordingly, it is desirable to improve air exchange for patients having chronic obstructive pulmonary diseases, such as chronic bronchitis and emphysema. It is especially desirable to achieve improved air exchange of emphysema patients without invasive open chest surgery and the associated complications.

SUMMARY OF THE INVENTION

The present invention pertains to methods of increasing gas exchange of the lungs of a patient. According to the present invention, gas exchange is increased by stiffening, strengthening, or destroying airway smooth muscle tone of at least one airway of a lung.

In accordance with another aspect of the present invention, a method includes: inserting an apparatus into an airway of a lung; and damaging tissue in the lung with the apparatus to increase gas exchange performed by the lung.

In accordance with a further aspect of the present invention, a method of increasing gas exchange performed by the lung, includes inserting an apparatus into an airway of a lung and causing trauma to tissue with the apparatus to cause fibrosis to stiffen the airway. The apparatus may include at least one of the following means of causing trauma to the

tissue: heating the tissue; cooling the tissue; delivering a liquid that cause trauma to the tissue; delivering a gas that cause trauma to the tissue; puncturing the tissue; tearing the tissue; cutting the tissue; applying ultrasound to the tissue; and applying ionizing radiation to the tissue.

Another aspect of the present invention pertains to a method including: inserting an apparatus into an airway of a lung; and destroying airway smooth muscle tone with the apparatus to increase gas exchange performed by the lung.

A further aspect of the present invention pertains to a method of increasing gas exchange performed by a lung. The method includes inserting an apparatus into an airway of a lung, and damaging airway tissue with the apparatus to thicken a wall of the airway.

The present invention also includes devices for mechanically damaging lung tissue.

The present invention provides advantages of a minimally invasive procedure for surgically treating the effects of pulmonary disease, such as chronic pulmonary disease, without the complications associated with conventional surgery.

BRIEF DESCRIPTION OF THE DRAWING

The invention will now be described in greater detail with reference to the preferred embodiments illustrated in the accompanying drawings, in which like elements bear like reference numerals, and wherein:

FIG. 1 is a cross-sectional view of an alveolar sack of a healthy lung;

FIG. 2 is a cross-sectional view of an alveolar sack of a diseased lung;

FIG. 3 is an illustration of a lung having a diseased lower portion prior to treatment according to the present invention;

FIG. 4 is a perspective view of the airway of a lung, wherein the smooth muscle tissue, alveolar sacks, and alveoli are illustrated;

FIG. 5 is a cross-sectional view of the airway of FIG. 4 taken along the line 5-5 of FIG. 4;

FIG. 6 is a schematic side view of lungs being treated with the treatment apparatus in accordance with one embodiment of the present invention;

FIG. 6A is a schematic cross-sectional view of the airway of FIG. 6 before treatment taken along the line 6A-6A of FIG. 6;

FIG. 6B is a schematic cross-sectional view of the airway of FIG 6A after being treated in accordance with one method of the present invention;

FIG. 7 is a cross-sectional view of an embodiment of a treatment apparatus that includes a brush for with the methods of the present invention;

FIG. 8 is a side cross-sectional view of the device illustrated in FIG. 7 after it has treated the airway of a lung;

FIG. 8A is a cross-sectional view of the device illustrated in FIG. 8 taken along the line 8A-8A of FIG. 8;

FIG. 9 is a side cross-sectional view of a treatment apparatus that includes a device for cutting or slicing the tissue of an air way of a lung in accordance with methods of the present invention;

FIG. 10 illustrates a partial side cross-sectional view of the embodiment illustrated in FIG. 9, where the treatment apparatus has treated the tissue of the lung;

FIG. 10A is a cross-sectional view of the device illustrated in FIG. 10 taken along the line 10A-10A of FIG. 10;

FIG. 11 is a side cross-sectional view of another embodiment of a treatment apparatus, where the treatment apparatus includes a plurality of members for slicing or cutting the air way of a lung in accordance with the methods of the present invention;

FIG. 12 illustrates the treatment apparatus of FIG. 11 in a deployed position;

FIG. 12A is a cross-sectional view of the device illustrated in FIG. 12 taken along the line 12A-12A of FIG. 12.

FIG. 13 illustrates a further embodiment of a treatment apparatus where the treatment apparatus includes a plurality of pins that puncture or penetrate the air way of a lung in accordance with the methods of the present invention;

FIG. 14 illustrates the treatment apparatus of FIG. 13 in a deployed position;

FIG. 14A is a cross-sectional view of the device illustrated in FIG. 14 taken along the line 14A-14Aof FIG. 14;

FIG. 15 illustrates an alternative embodiment of the treatment apparatus illustrated in FIGS. 13 and 14 for use with the methods of the present invention;

FIGS. 16-20 illustrate embodiments of treatment apparatus that deliver a fluid to the airway to treat the lungs in accordance with the methods of the present invention;

FIG. 21 is a side view of a bronchoscope that may be used to deploy the above-illustrated treatment apparatus when practicing the present invention; and

FIG. 22 is a cross-sectional view of the device illustrated in FIG. 21 taken along the line 22-22 of FIG. 21.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

In the following description, like reference numerals refer to like parts.

FIG. 3 illustrates human lungs 20 having a left lung 30 and a right lung 32. A diseased portion 31 is located at the lower portion or base of the left lung 30 (indicated by the volume of the lung below the dashed line on the left lung). In some cases, the diseased portions of an unhealthy lung are not generally located in discrete areas. That is, the diseased portions may not be distributed heterogeneously, and are more homogeneous.

As illustrated in FIG. 3, the trachea 22 extends down from the larynx and conveys air to and from the lungs. The trachea 22 divides into right and left main bronchi 24, which in turn form lobar, segmental, and sub-segmental bronchi or bronchial passageways. Eventually, the bronchial tree extends to the terminal bronchiole. At the terminal bronchiole, alveolar sacs 26 contain alveoli 28 that perform gas exchange as humans inhale and exhale.

FIG. 4 illustrates an airway 25 of the lung 30 or 32 in greater detail. The airway 25 is a bronchial tube, air passage, lumen, bronchial airway, or respiratory bronchiole of the lungs 20. The airway 25 includes smooth muscle tissue that helically winds around the bronchiole to define a duct of the airway 25 through which air may be inhaled and exhaled during operation of the lung. The smooth muscle tissue is arranged around the airways in a generally helical pattern with pitch angles ranging from about -30 to about +30 degrees. As the airway 25 branches deeper into the lung, more and more alveolar sacs 26 and alveoli 28 appear, as shown in FIGS. 3 and 4.

FIG. 5 illustrates a light microscopic cross-section of the tissue of the airway 25 taken along the line 5-5 of FIG. 4. FIG. 5 illustrates a cross section of the tissue of the airway 25 which is a collection of cells and intercellular substances that surround the cells, together defining the airway 25. The airway 25 defines an airway duct 39 through which gases are inhaled and exhaled. The airway 25 of FIG. 5 is a medium sized bronchus having a duct diameter D1 of about 3 mm. The airway 25 includes a folded inner surface or epithelium 38 surrounded by stroma 23 and the smooth muscle tissue 27. The airway 25 also has mucous glands 34 and cartilage 30 surrounding the smooth muscle tissue. Nerve fibers and blood vessels 36 also surround the airway. Hence, as shown in FIG. 5, the smooth muscle tissue 27 is part of the overall tissue of the airway 25.

Referring again to FIG. 3, the diseased portion 31 of the lung 30 is located at the lower portion or base of the lung. By way of example, it can be considered that this diseased portion 31 has been stricken by emphysema. The emphysematous portion 31 of the lung 30 generally includes sections in which the walls between the adjacent alveoli 28 have deteriorated to a degree that the lung tissue looks like Swiss cheese in cross section. When this occurs, pulmonary function is impaired to a great degree.

The pulmonary system utilizes two simple mechanisms, air exchange into and out of the lungs 20 and gas exchange into and out of the blood. In patients with emphysema, both of these mechanisms are impaired, leading to dyspnea (shortness of breath), limitations in physical activities, and increased incidence of related diseases. To improve their condition, either or both of these impairments need to be improved. One way to address this is by restoring some of the lost air exchanging ability.

Air exchange is created by movement of muscles that increase and decrease the pressures around the lungs. Inspiration occurs when a decrease in pressure around the lungs to below atmospheric pressure expands the lungs, which in turn causes the pressure in the terminal end points of the airways (the alveoli 28) to drop below atmospheric. This pulls the air into the alveoli 28 through the conducting airways 25.

Exhalation is a passive process. Normal exhalation occurs when the muscles relax, allowing the natural elasticity of the lung structure to expel the air from within. In addition to making up the driving force to expel air from the lungs, the elasticity also mechanically helps keep conducting airways from collapsing. It is the loss of elasticity of lung tissue that leads to the condition known as "dynamic airway collapse".

In more detail, airway obstruction in the emphysematous patient has two components, "small airways disease" and dynamic airway collapse of the mid-sized airways. Both contribute to the patient's inability to get adequate amounts of air to and from the alveoli 28, which are the gas exchanging membranes in the lungs. Small airways disease is primarily caused by mucous plugging and inflammation of the small (less than 2mm in diameter) airways, whereas dynamic airway collapse of the mid-sized airways (3mm-6mm) is mechanical in nature.

The mechanics of mid-size airway "patency" are dictated by four forces being in balance with one another. If the balance of those forces shifts, airway collapse will occur. Specifically, these forces are: (1) air pressure inside the airway in question, (2) air pressure in the alveoli directly surrounding that airway, (3) "tethering" of the airway by the

surrounding tissue (parenchyma) and (4) stiffness of the airway wall itself. It is inherent in the movement of gases within the lungs that the pressure in the alveoli 28 directly surrounding the airway 25 must be higher than that within the airway itself during exhalation. Otherwise, no air would move from the alveoli 28 to, and through, the airway 25 on its way out of the lung. Since this inherent pressure differential would collapse an airway 25 if that airway were made of a very flexible material, there must be some mechanical strength built into the airway system to oppose this collapse in healthy people. This strength comes from both the stiffness of the airway wall and the tethering action of the surrounding parenchyma.

In patients with emphysema, the number of parenchymal tethers touching each airway is reduced. This in turn reduces the tethering forces that maintain the airway open. With these tethering forces reduced, the only thing keeping the airway open is the stiffness of the airway wall. In an emphysematous lung, this is often not enough, and the airways collapse during exhalation. Embodiments of the present invention aim to increase the strength of the airway walls to keep the airway open, which will increase gas exchange.

By strengthening the airway walls of an emphysematous lung, the balance of forces during exhalation is shifted back toward keeping the airways open. In short, stiffening the airway wall helps prevent airway collapse during exhalation, which will thus result in an increase in airflow and gas exchange.

One way to achieve this stiffening is to thicken the walls themselves. The present invention is based in part on the discovery that the airway 25 is strengthened because of the natural formation of fibrotic tissue, such as scar tissue, in response to trauma or injury. Fibrosis is the formation of fibrous or fibrotic tissue as a reparative or reactive process, i.e., regrowth of tissue after injury. The formation of fibrotic tissue essentially deposits additional tissue to the airway, which strengthens the wall of the airway. This stimulation of additional material will increase the thickness of the airway wall, thus strengthening the airway to help prevent the airway from collapsing during exhalation. The airway 25 is stiffened because the fibrotic tissue is thicker than the previous diseased tissue supporting the airway. As described below, the trauma can be caused by damaging the airway tissue, such as by delivering heat to the airway and/or by mechanical insult to the airway tissue.

By strengthening the airway walls of an emphysematous lung in accordance with the embodiments of the present invention, the balance of forces during exhalation is shifted back toward keeping the airways open. Stiffening airway wall by stimulating the

deposition of fibrotic tissue helps prevent airway collapse during exhalation, and will thus result in an increase in airflow. In general, the greater the scarring or injury, the greater the build-up of fibrotic tissue. The thicker the airway wall due to build-up of fibrotic tissue, the less likely that it will collapse as it may have prior to treatment according to the present invention.

If the airway tissue is injured to such an extent that the airway wall thickens, it is preferable not to create so much fibrotic tissue that the airway closes. That is, it is preferable that the formation of fibrotic tissue does not cause stenosis. Stenosis may be prevented by controlling the extent of injury or damage to the airways of the lung. It is also preferable not to ablate or vaporize large amounts of airway tissue such that the airway loses its structure. Hence, it is preferable to damage enough airway tissue to cause fibrotic tissue to develop and stiffen the existing airway wall, rather than completely destroying the existing airway wall to define a new cavity, and rather than destroying so much tissue that a mass of scar tissue blocks the airway.

The gas exchange of the lung 20 can also be increased in accordance with the embodiments of the present invention by destroying the airway smooth muscle tone. Smooth muscle tone refers to ability of the smooth muscle of the airway to respond to signals that trigger the airway smooth muscle to continually and partially contract. By destroying the smooth muscle or disrupting the smooth muscle's ability to respond to such signals, the contraction force is removed and the airway will become larger.

When one inhales, the pressure in the airway is higher than the alviolar pressure that acts on the outside of the airway. This being the case, a "floppy" or diseased airway will remain open on inspiration. However, as described above, upon expiration, the alviolar pressure builds and at some point exceeds the air pressure in the airway. In this state, a floppy airway, will be more prone to collapse and inhibit the flow of air out of the alveoli. The smooth muscle tone may further restrict the airway diameter. Hence, the removal or destruction of at least some of the smooth muscle tone will beneficially increase gas exchange during the expiration cycle.

Thus, the present invention strives to relieve the effects of emphysema and other forms of pulmonary disease by increasing the efficiency of gas exchange in the lung 20. Generally speaking, this may be achieved by inserting an apparatus into an airway of the lung through the trachea 22, and then damaging tissue of the airway 25 to cause fibrosis to strengthen the airway and/or to destroy smooth muscle tone of the airway.

The following description of the treatment apparatus for use with the embodiments of the present invention can be employed to treat a bronchial tube regardless of whether the tube lumen has collapsed or not. Specifically, the devices can be used to treat bronchial tubes that have not collapsed, are partially collapsed, or are fully collapsed. Moreover, bronchial tubes may exhibit different degrees of closure depending on the state of respiration. For example, a bronchial tube may have a fully expanded lumen during inhalation but partially or completely closed during exhalation.

FIG. 6 is a schematic view of the lung 20 being treated with a treatment apparatus 40 in accordance with a method of the present invention. The preferred apparatus 40 is an elongated member that may be electronically or manually controlled by a surgeon or controller 42 to damage lung cells to cause fibrosis to stiffen the airway and/or to destroy smooth muscle tone of the airway so as to increase gas exchange performed by the lung. As described further below, the damaging of cells of airway tissue and/or destruction of smooth muscle tone of the airway with the apparatus 40 may be accomplished by any one of, or combinations of, the following:

(1) heating the tissue;

(2) cooling the tissue;

(3) delivering a liquid that damages the tissue;

(4) delivering a gas that damages the tissue;

(5) puncturing the tissue;

(6) tearing the tissue;

(7) cutting the tissue;

(8) applying ultrasound to the tissue;

(9) applying ionizing radiation to the tissue;

(10) other methods that cause trauma to lung cells to cause fibrosis to stiffen the airway so as to increase gas exchange performed by the lung; and

(11) other methods that destroy smooth muscle tone of the airway so as to increase gas exchange performed by the lung. A more detailed description of the methods of stiffening the airway 25 and destroying the airway smooth muscle tone to increase gas exchange follows.

FIG. 6A is a representational cross-sectional view of the airway 25 of the lung 32, taken along the line 6A-6A in FIG. 6, during expiration before it has been treated with the apparatus 40, while FIG. 6B is a representational cross-sectional view of the airway 25

during expiration after it has been treated with the apparatus 40 in accordance with a preferred method of the present invention FIG. 6B.

As illustrated in FIG. 6A, the airway 25 is partially collapsed due to pulmonary disease, such as described earlier. In this state, air exchange is adversely affected. In FIG. 6B, the treatment apparatus 40 has damaged the tissue of the airway 25 so as increase the thickness of the airway wall. More particularly, the airway 25 has been strengthened because of the natural formation of fibrotic tissue in response to trauma or injury. The formation of the fibrotic tissue has deposited additional tissue to the airway, which strengthens the wall of the airway. Thus, the airway wall shown in FIG. 6B is thicker than the airway wall shown in FIG. 6A. This increased thickness of the airway wall strengthens the airway to help prevent the airway from collapsing during exhalation. Accordingly, the airway illustrated in FIG. 6B is not collapsed to the same extent as the untreated airway illustrated in FIG. 6B. Hence, if the lung 32 is stricken with emphysema, the previously described balance of forces during exhalation is shifted back toward keeping the airway 25 open, which helps prevent airway collapse during exhalation, and will thus result in an increased airflow and gas exchange.

FIG. 6 is cross sectional view of lungs being treated with a treatment apparatus 40 in accordance with one embodiment of the present invention. The treatment apparatus 40 is an elongated member for accessing a treatment site in an airway of the lungs. The treatment may be delivered by the treatment apparatus 40 in a variety of treatment patterns to achieve a desired response. Examples of patterns are discussed in further detail below. The treatment which is delivered by the treatment apparatus 40 may be any of a variety of types including, but not limited to, radiant, laser, radio frequency, microwave, heat energy, or mechanical energy (such as in the form of cutting or mechanical dilation), delivery of a fluid or other chemical.

FIGS. 7-20 illustrate embodiments of treatment apparatus or devices 40AQ-40AX that can be used to destroy airway smooth muscle tone and/or damage airway tissue to induce fibrosis according to the present invention. These are just some of the examples of the type of treatment apparatus which may be used to perform the methods according to the present invention. It should be recognized that each of the treatment apparatus described below can be modified treat tissue in different patterns, depending on the treatment to be performed. The treatment apparatus may be actuated continuously for a predetermined period while stationary, may be pulsed, may be actuated multiple times as they are moved

along an airway, may be operated continuously while moving the treatment apparatus in an airway to achieve a "painting" of the airway, or may be actuated in a combination of any of these techniques. The particular application pattern desired can be achieved by configuring the treatment apparatus itself or by moving the treatment apparatus to different desired treatment locations in the airway.

The airway smooth muscle tone can be destroyed and the cells of the airway tissue of the airway 25 can be damaged by applying the treatment device to the tissue 27. The damaging of the airway tissue induces fibrosis so as to strengthen the airway. A pattern for treatment can be chosen from a variety of patterns including longitudinal stripes, circumferential bands, helical stripes, and the like as well as spot patterns having rectangular, elliptical, circular or other shapes. The size, number, and spacing of the treatment bands, stripes, or spots are chosen to provide a desired clinical effect of strengthening the airway wall or destroying the smooth muscle tone of the airway without completely destroying the airway or obstructing the airway.

It is understood that other forms of energy such as alternating current, microwaves, ultrasound, and light (either coherent (e.g., laser) or incoherent (e.g., light emitting diode or tungsten filament) can be used), and that the thermal energy generated from a resistive coil, a hot fluid element (e.g., circulating liquids, gases, combinations of liquids and gases, etc.), a curie point element, or similar elements can be used as well. Regardless of the source, energy delivered to the lumen wall of the obstructed airway passage should be such that all of the airway tissue is not completely ablated.

When treating a person with obstructed air passages, a preliminary diagnosis is made to identify the air passages or bronchial tube that can be treated. In treating a particular site, excessive fluid is first removed from the obstructed air passage by conventional means such as with a suction catheter. Thereafter, the treatment apparatus is maneuvered to the treatment site. Depending on the diameter of the lumen of the bronchial tube, the device can be positioned directly at the treatment site or it can be positioned into place with a bronchoscope. The device may include elongated shafts and outer catheter whichare preferably made of a flexible material so that the catheter can be maneuvered through a bronchoscope. A bronchoscope is a modified catheter which includes an illuminating and visualization instrument for monitoring the treatment site and a channel for passing instruments (e.g., the treatment apparatus) into the bronchial tubes.

In operation, the bronchoscope is advanced from the person's nasal or oral cavity, through the trachea, main stem bronchus, and into an obstructed air passage. The treatment apparatus is advanced forward through the bronchoscope to expose the tip of the treatment apparatus before the treatment is applied. Depending on the size of the treatment apparatus, the treatment apparatus can be moved to another position for further treatment of the air passage. This process can be repeated as many times as necessary to form a series of patency bands supporting an air passage. This procedure is applied to a sufficient number of air passages until the physician determines that he is finished. As is apparent, the procedure can be completed in one treatment or multiple treatments. The invention is also directed to the demonstration or instruction of the inventive surgical techniques including, but not limited to, written instructions, actual instructions involving patients, audio-visual presentations, animal demonstrations, and the like.

FIGS. 7 and 8 illustrate another embodiment of a treatment apparatus 40AQ that may be used to treat a lung according to the present invention. The treatment apparatus 40AQ, like the previously described treatment apparatus, damages tissue of the airway 25 so as to induce fibrosis and add thickness to the airway wall. The treatment apparatus 40AQ also destroys the airway smooth muscle tone to increase gas exchange. With the treatment apparatus 40AQ, a bristled brush 4000 having a plurality of bristles 4002 is introduced into the airway 25 so as to puncture the airway wall with the bristles 4002. The bristles 4002 may be needles, pins, or other similarly shaped members. The bristles 4002 are located at the distal end of an elongated member 4004. The bristles 4002 extend radially outward from the outer surface of the distal end of the elongated member 4004, and are preferably flexible. The brush 4000 has at least one bristle 4002 that may be manipulated to damage the tissue of the airway 25.

As shown in FIG. 7, the brush 4000 is inserted through a tube-like member or cannula 4006 which has been inserted into the airway 25. Because the outer diameter of the brush 4000 (as measured about the most distal ends or tips of the bristles 4002) is greater than the interior diameter of the cannula 4006, the bristles 4002 bend against the interior surface of the cannula 4006 when the brush 4000 is located within the interior of the cannula 4006.

FIG. 8 illustrates the brush 4000 after it has been pushed through the most distal opening 4005 of the cannula 4006. Hence, as shown in FIG. 8, the brush 4000 is located at least partially outside of the cannula 4006. As also shown by FIG. 8, when the brush 4000

exits the outlet 4005 of the cannula 4006, the bristles 4002 will return radially outward to their original straight configuration, rather than the bent configuration shown in FIG. 7 where the bristles interfere with the interior surface of the cannula 4006. Hence, the bristles 4002 extend radially outward toward the wall of the airway 25 when the distal end of the brush is forced through the opening of the cannula. As shown in FIG. 8, the bristles 4002 have penetrated the wall of the airway 25 to thus cause trauma to the tissue. Once the brush 4000 of the treatment apparatus 40A extends from the outlet 4005 of the cannula 4006, the brush 4000 may be moved along the length of the duct as illustrated by the arrow 4007 in FIG. 8 so as to cause further trauma and damage to the airway 25. Additionally, as also illustrated by the arrow 4009 in FIG. 8, the brush 4000 may be rotated while in the airway 25 so as to cause damage to the airway 25. The brush 4000 may be moved along the select lengths of the airway 25 to damage predetermined portions of the airway, as desired. After the desired damage has been completed, the brush 4000 may be retracted back through the opening 4005 of the cannula 4006 such that undesired damage is not caused to other portions of the airway 25 when the brush 4000 is removed from the airway and eventually the lung.

The bristles 4002 are preferably the flexible pins illustrated in FIGS. 8, and are preferably made of a metallic material such as stainless steel. The bristles preferably have a caliber that permits them to be easily bent and resiliently return to their original position after being bent. However, the bristles 4002 may take other forms. For example, the bristles 4002 may be rigid and substantially not elastic such that they are not easily bendable. That is, the bristles may be needle-like members. In this case, the length of each needle-like member must be sufficiently small so that the brush 4000 may travel through the cannula 4006, because the needle-like members will not bend in the cannula 4006 when contacting the interior surface of the cannula 4006. The brush 4000 has needle-like members which may be manipulated in the airway 25 so as to cause trauma to the airway wall.

The bristles 4002 preferably each have a sharp point or tip that will puncture the airway wall to cause damage and thus induce fibrosis and/or destroy smooth muscle tone. However, the tips of the bristles may be blunt such that the bristles will tear or rip the airway, rather than simply puncturing the airway wall. In this case, the tearing action will damage cells of tissue to induce a fibrotic response. Alternatively, the bristles 4002 may be

razor-like members having a sharp longitudinal edge that slices the airway 25 to cause damage.

FIGS. 9 and 10 illustrate another embodiment of a treatment apparatus 40AR for use with the method of the present invention. The treatment apparatus 40AR causes damage to the airway 25 by preferably cutting through the airway wall. The treatment apparatus 40AR includes a cutting device 4100 having a plurality of elongated blades 4102, 4103. As shown by the end view in FIG. 10A, the elongated blades 4102, 4103 are circumferentially spaced at four locations along the exterior surface of an inner rod 4104. However, additional blades may be included. For example, the blades may be circumferentially spaced at eight locations along the exterior surface of the inner rod 4104.

The inner rod or tube 4104 is located at least partially inside the interior of an outer tube or cannula 4106. As shown by the arrow 4107 in FIG. 10, the inner tube 4104 is movable within the interior of the outer tube 4106 along the lengthwise direction of the outer tube 4106. As shown in FIGS. 9 and 10, each of the elongated blades 4102 is pivotally connected to the inner tube 4104 by a pivot connection 4112 located at the most distal end of the inner tube 4104 so as to be rotatable about the pivot connection 4112. Each of the elongated blades 4102 located toward the distal end of the inner rod 4104 is also pivotally connected by another pivot connection 4110 to another elongated blade 4103. Hence, the pivot connection 4110 defines a point about which each of the blades 4102, 4103 rotates. The elongated blade 4103 is pivotally connected to the outer tube 4106 by a further pivot blade connection 4108 so as to be rotatable about the pivot connection 4108. Hence, the blades 4102 and 4103 are movable in the direction shown by the arrow 4109 in FIG. 10 when relative motion occurs between the inner tube 4104 and the outer tube 4106, preferably when the inner tube 4104 and/or the outer tube 4106 are moved in the direction of the arrow 4107. For example, when the inner tube 4104 and the outer tube 4106 are moved from the positions illustrated in FIG. 9 to the positions illustrated in FIG. 10, each of the elongated blades 4102 and 4103 will pivot about the pivot connections 4108, 4110, 4112 such that the elongated blades 4102, 4103 move toward the wall of the airway 25 and cut through tissue of the airway to induce fibrosis. The more the most distal end of the inner tube 4104 having the pivot connection 4112 and the most distal end of the outer tube 4106 having the pivot connection 4108 are moved toward each other, the more the blades 4102, 4103 will rotate about the pivot connections 4112, 4110, 4108. In this manner, the elongated blades 4102, 4103 may be caused to cut through the tissue of the airway 25 so as

to cause trauma. Preferably, the elongated blades 4102, 4103 will damage tissue 27 such that scar tissue develops to thicken the wall of the airway and thus strengthen the airway. As shown in FIG. 10, the elongated blades 4102, 4103 have cut or sliced through the tissue of the airway.

The elongated blades 4102, 4103 may be repeatedly collapsed and expanded as shown in FIGS. 9 and 10 so as to cause multiple cuts to the airway tissue, as desired. Additionally, the elongated blades 4102, 4103 may be moved in the longitudinal direction of the airway wall while the blades are in the expanded position shown in FIG. 10 so as to further slice the airway tissue. Likewise, the cutting apparatus 4100 may be rotated in the airway 25 as shown by the arrow 4105 in FIG. 10 so as to cut and/or tear the tissue of the airway 25.

The elongated blades 4102, 4103 are preferably thin razor-like elongated members of stainless steel that easily slice through the airway tissue. However, the elongated blades 4102, 4103, may take other configurations. For example, the elongated blades 4102, 4103 may be rods having a serrated surface or surfaces that cut or tear through the airway tissue. Additionally, the elongated blades 4102, 4103 may each include a plurality of pins that function to penetrate or puncture the airway tissue to destroy smooth muscle tone and/or induce fibrosis to strengthen the airway wall and thus improve gas exchange efficiency.

FIGS. 11-12 illustrate a further embodiment of a treatment apparatus 40AS for use with the method of the present invention. The treatment apparatus 40AS includes a slicing device 4200 that slices through the airway tissue to destroy smooth muscle tone and/or damage lung tissue and induce fibrosis to strengthen the airway wall. The slicing device 4200 includes a plurality of elongated slicing members 4202 that each include a razor edge 4208 located at the most distal end of the slicing members. The slicing members 4202 are preferably elongated metallic members that protrude from the an outlet 4201 of an inner tube 4204. The slicing members 4202 are movable in the inner tube 4204 along the lengthwise direction of the inner tube 4204 as shown by the arrows 4207 illustrated in FIG. 12. The inner tube 4204, similar to the previously described embodiments, is located within an outer tube or cannula 4206. The slicing members 4202 may be forced out of an opening 4203 of the outer tube 4206 at the most distal end of the outer tube such that they project outwardly from the end of the outer tube 4206. FIG. 11 illustrates the slicing members 4202 located completely inside of the outer tube 4206, while FIG. 12 illustrates the slicing members 4202 after they have been moved out of the opening 4203 of the outer

tube 4206. The slicing members 4202 may be annually forced through the opening 4203 or automatically caused to move through the opening 4203 by a controller (not illustrated).

As illustrated in FIGS. 11 and 12, when the slicing members 4202 are moved out of the opening 4203, they bend or curve away from the longitudinal axis of the outer tube 4206 such that the members slice through the airway tissue of the airway 25. Hence, the slicing members 4202 are preferably biased to bend away from the longitudinal axis of the outer tube 4206. That is, each of the slicing members acts like a spring and moves toward the airway wall after exiting the outlet 4203.

The slicing members 4202 may be attached to the inner tube 4204 such that the slicing members 4202 move with the inner tube 4204 when the inner tube is moved relative to the outer tube 4206. Additionally, the slicing members 4402 may not be attached to the inner tube 4204 such that they are movable relative to the inner tube 4204, as well as the outer tube 4206. As shown by the arrow 4209 in FIG. 11, the slicing members 4202 can be rotated relative to the airway 25 during the treatment process so as to slice, cut, or tear through the airway wall to cause further trauma.

Although the embodiment shown in FIGS. 11-12 includes only four slicing members 4202, other numbers of slicing members are contemplated. For example, the treatment apparatus 40AS can slice the airway tissue with 8, 16, 32, 56, or other numbers of slicing members 4202 that are movable relative the airway 25 so as to cause damage to the airway tissue of the lung.

The slicing members 4202 can be moved to repetitively slice through the tissue of the airway 25 so as to define a plurality of sliced areas 4210. In general, the greater the number of sliced areas 4210 made with the treatment apparatus 40AS, the greater the damage of smooth muscle tone and the greater the fibrotic response, which will thicken the airway wall and strengthen the airway wall to thus increase gas exchange.

The slicing members 4202 are preferably thin and elongated members having a razor edge 4208. However, the slicing members 4202 can be other configurations. For example, each of the slicing members 4202 may include a pin point rather than a razor edge. Additionally, each of the slicing members 4202 may include serrations or a razor edge along the elongated edges or sides of the slicing members 4202, which may extend the entire length of the slicing member or only along predetermined portions of the length.

FIGS. 13- 14 illustrate further embodiments of treatment apparatus 40AT for use with the present invention. As shown in FIG. 13, the treatment apparatus 40AT includes a

balloon 4312 having a plurality of pins 4308 attached to the outer surface of the balloon. The balloon 4312 is similar to the previously described balloons and may be fabricated from like materials. The balloon 4312 is partially located within an inner tube 4304, as well as a containment sheath 4309. The balloon 4312 extends from the outlet end of the inner tube 4304. As shown in FIG. 14, the inner tube 4304 is connected to a fluid supply 4314, which can supply a pressurized gas or fluid to the interior of the tube 4304 and hence the interior of the balloon 4312 to cause the balloon to expand as shown in FIG. 14.

The sheath 4309 that surrounds or encases the balloon 4312 includes a plurality of openings 4302 that extend through the cylindrical wall of the sheath 4309. Hence, the openings 4302 communicate the exterior of the sheath 4309 with the interior of the sheath. The balloon 4312 is attached to the sheath 4309 at the most distal end 4310 of the sheath. The openings 4302 in the sheath 4309 are located at locations on the exterior surface of the sheath 4309 such that when the balloon 4312 is expanded the pins 4308 will travel through the openings 4302 and protrude from the exterior surface of the sheath 4309. That is, the openings 4302 are spaced along the length and the circumference of the sheath 4309 the same distance that the pins 4308 are spaced along the length and circumference of the balloon 4312. Hence, when the balloon 4312 is expanded upon application of pressure by the fluid supply 4314, the pins will move radially toward the airway and extend through the openings 4302. When the balloon 4312 has been fully expanded as shown in FIG. 14, the pins 4308 will protrude through the openings 4302 and will puncture the tissue of the airway 25 so as to destroy smooth muscle tone and/or induce fibrosis and strengthen the airway.

The sheath 4309 is preferably formed of a rigid material, such as hard plastic, so that the location of the openings 4302 relative to the location of the pins 4308 on the balloon 4312 remains relatively constant during the treatment process. The sheath 4309 is preferably attached to the outer tube 4306 such that the sheath 4309 will move when the outer tube 4306 is moved. Hence, after the balloon has been expanded to cause pins 4308 to extend through the openings 4302 and puncture the airway tissue, the sheath 4309, the outer tube 4306, the balloon, and the pins 4308 may be moved in the longitudinal direction of the airway 25 so as to further tear or slice through the airway tissue. Likewise, as shown by the arrow 4307 shown in FIG. 14, the sheath 4309 may be rotated so as to rotate the pins 4308 to cause further damage to the tissue of the airway.

As shown in FIGS. 13 and 14, the pins 4308 are located on diametrically opposite sides of the balloon 4312, as are the openings 4302 of the sheath 4309. However, the balloon 4312 may include further rows and columns of pins 4308 and the sheath may include further rows and columns of openings 4302, as illustrated by the embodiment of the treatment apparatus 40AT' illustrated in FIG. 15. As shown in FIG. 15, the balloon 4312' includes eight rows of pins 4308 equally spaced along the length and circumference of the balloon 4312'. Hence, the sheath 4309' also includes correspondingly located openings 4302 that the pins 4308 may protrude through when the balloon 4312' is expanded. Other numbers of pins 4308 and openings 4302 are also contemplated.

The balloons of the embodiments illustrated in FIGS. 13-15 can be repeatedly expanded and contracted so as to cause multiple punctures to the airway tissue to destroy the airway smooth muscle tone and induce fibrosis and hence stiffen the wall of the airway. Additionally, the pins 4308 can be other configurations. For example, a plurality of razors, knifes, or blunt members can be attached to the balloon such that the airway tissue is sliced, cut, or torn when the balloon is expanded.

FIG. 16 illustrates another embodiment of a treatment apparatus 40AU that may be used according to the present invention. The treatment apparatus 40AU includes a balloon 4412, which is illustrated in its expanded state in FIG. 16. The balloon 4412 includes a plurality of openings 4402 that communicate the exterior of the balloon with the interior of the balloon. The openings 4402 are a plurality of small holes that extend through the wall of the balloon 4412. The balloon 4412 is attached to the end of a tube or cannula 4406. The interior of the balloon 4412 may be filled with a liquid or gas from the fluid supply 4408. Hence, the fluid supply 4408 is in communication with the interior of the balloon 4412 through the tube 4406. The balloon may be expanded as shown in FIG. 16 by pressurizing the interior of the balloon 4412 with a liquid or gas from the supply 4408. The liquid or gas supplied from the supply 4408 will exit the balloon 4412 through the openings 4402 located in the balloon. The expanded balloon 4412 contacts with the airway wall. Hence, when the fluid exits the balloon 4412 through the openings 4402, it will contact the tissue of the airway 25. The fluid that exits the balloon 4412 may be a heated liquid or gas, similar to the above-described embodiments that destroy cells of the airway tissue by the application of heat. The fluid is preferably a biocompatible liquid, such as liquid saline or air. Additionally, the fluid delivered by the supply 4408 may be cold liquid or gas that destroys the airway tissue by removing heat from the airway tissue when it passes through

the openings 4402 of the balloon 4412. In a preferred embodiment of the treatment apparatus 40AU, the liquid or gas supplied by the supply 4408 is cooled to a temperature that destroys airway smooth muscle tone and/or damage airway tissue to induce a fibrotic response to strengthen the airway 25. The liquid or gas delivered by the treatment apparatus 40AU can also destroy tissue cells by chemically reacting with the tissue. For example, the treatment apparatus 40AU can deliver an acid to the airway tissue to cause trauma to the tissue.

Although the expanded balloon 4412 illustrated in FIG. 16 contacts the wall of the airway 25, the balloon 4412 can be smaller than the airway 25 such that it does not contact the airway wall when expanded.

FIGS. 17 and 18 illustrate another embodiment of a treatment apparatus 40AV that can be used to perform the present method of the invention. The treatment apparatus 40AV, like the apparatus 40AU illustrated in FIG. 16, includes a balloon 4512. The balloon 4512 is illustrated in its collapsed condition in FIG. 17, and is illustrated in its expanded condition in FIG. 18. As shown in FIGS. 17 and 18, the balloon 4512 includes a plurality of tubes 4504 attached to the exterior surface of the balloon 4512. The interior of the balloon 4512 is not in communication with the interior of the tubes 4504. The plurality of tubes 4504 are preferably circumferentially spaced about the exterior cylindrical surface of the balloon 4512. Each of the tubes 4504 extends along the longitudinal length of the balloon 4512 and through the interior of a tube or cannula 4508. Like the embodiment illustrated in FIG. 16, the balloon 4512 may be inflated by a fluid supply 4514 which supplies a gas or liquid to the interior of the balloon 4512 to cause it to expand to the position illustrated in FIG. 18. However, unlike the embodiment illustrated in FIG. 16, the expansion of the balloon 4512 does not cause a liquid or gas to be delivered to the wall of the airway 25. Rather, a separate fluid supply 4510 delivers a liquid or gas to the interior of each of the tubes 4504.

The liquid or gas delivered by the fluid supply 4510 travels through the interior of the elongated tubes 4504 and out of a plurality of openings 4502 spaced along the length of each of the tubes 4504. The openings 4502 are equidistantly spaced along the length of the tube 4504. Hence, after the balloon is expanded by pressure from the supply 4514, the supply 4510 may supply a liquid or gas to the interior of the tubes 4504 and out of the openings 4502 such that the liquid or gas from the supply 4510 contacts the airway tissue. As with the embodiment described above in reference to FIG. 16, the liquid or gas supplied

from the supply 4510 will damage the airway tissue. The fluid or gas delivered through the holes 4[illegible]2 damages tissue 27 to induce fibrosis and thicken the wall of the airway 25 so as to strengthen the airway wall and increase the gas exchange efficiency of the lung. The fluid or gas can also destroy the smooth muscle tone to increase gas exchange.

FIG. 19 illustrates an additional embodiment of a treatment apparatus 40AW for use with the methods of the present invention. The treatment apparatus 40AW includes a tube or cannula 4604 having a plurality of holes 4602 located at a most distal end of the tube 4604. The plurality of holes 4602 form a plurality of columns and rows about the circumference of the tube 4604, as illustrated in FIG. 19. The holes 4602 deliver a fluid, such as that described above in reference to FIGS. 16-18 to the tissue of the airway 25 to damage cells and induce fibrosis. As shown in FIG. 19, a gas supply 4610 and/or a liquid supply 4612 may deliver a fluid to the interior of the tube 4604, through the holes 4602, and to the tissue of the airway 25. In this manner, a gas and/or a fluid will destroy smooth muscle tone and/or damage tissue to induce fibrosis and increase the gas exchange efficiency of the lung.

FIG. 20 illustrates a further embodiment of a treatment apparatus 40AX for use with the methods according to the present invention. The treatment apparatus 40AX, like the embodiments illustrated in FIGS. 16-20, delivers a liquid or a gas to the airway 25 so as to damage cells of the airway tissue. In the embodiment illustrated in FIG. 20, an inner tube 4702 is located within an outer tube 4704. The inner tube 4702 may be connected to a gas supply or liquid supply 4710. Likewise, the outer tube 4704 may be connected to a gas supply or liquid supply 4712. The fluid delivered to the interior of the inner tube 4702 from the supply 4710 exits the outlet 4708 at the distal end of the inner tube 4702. The fluid delivered from the supply 4712 exits the outlet 4706 at the most distal end of the outer tube 4704. Because there are two separate tubes 4702, 4704, and two separate supplies 4710, 4712, two separate liquids, two separate gases, or a combination of liquids and gases may be delivered to the airway tissue to cause trauma to destroy smooth muscle tone and/or cause fibrosis and strengthen the airway 25. For example, two liquids or gases may be combined at the outlets 4706, 4708 to cause a chemical reaction that damages the cells of the airway tissue to induce fibrosis.

FIGS. 21 and 22 illustrate a bronchoscope, such as described earlier, that may be used with each of the above-described treatment apparatus 40. The bronchoscope 5000 has a treatment apparatus 40 slidably positioned within a lumen of the bronchoscope. The

bronchoscope also includes an image-transmitting fiber 5008 and illuminating fiber 5020. Any conventional bronchoscope with an appropriately sized and directed working lumen may be employed. The image transmitting fiber collects light from the distal end of the treating apparatus and directs the light to a viewing apparatus (not shown) for displaying an image of the air passage. The bronchoscope may have a panning system which enables the tip to be moved in different directions. In treating a particular site, excessive fluid is first removed from the obstructed air passage by conventional means such as with suction. Thereafter, the bronchoscope as illustrated in FIGS. 21 and 22 is advanced from the person's nasal or oral cavity, and through the trachea, main stem bronchus, and into an air passage. The treatment apparatus 40 is advanced forward from the bronchoscope such that the treatment apparatus may be used to destroy airway smooth muscle tone and/or cause damage to airway tissue to induce fibrosis and strengthen an airway of the lung. This procedure is applied to a sufficient number of obstructed air passages until the physician determines that the treatment is finished. As is apparent, the procedure can be completed in one treatment or multiple treatments. The bronchoscope and the treatment apparatus 40 are then removed from the patient.

Preferably, regarding the variations of the invention using a balloon, the exact amount of inflation may be determined by the operating surgeon who monitors the balloon expansion by means of endoscopy, or other suitable imaging methods of the art. The balloon of the treatment apparatus described herein may be constructed of non-elastic material that is initially folded and/or collapsed. In this non-inflated state, the diameter of the balloon is small enough that the balloon can be positioned inside an aperture or working channel of a bronchoscope.

The principles, preferred embodiments and modes of operation of the present invention have been described in the foregoing specification. However,. the invention which is intended to be protected is not to be construed as limited to the particular embodiments disclosed. Further, the embodiments described herein are to be regarded as illustrative rather than restrictive. Variations and changes may be made by others, and equivalents employed, without departing from the spirit of the present invention. Accordingly, it is expressly intended that all such variations, changes and equivalents which fall within the spirit and scope of the present invention as defined in the claims be embraced thereby.

WHAT IS CLAIMED IS:

1. An apparatus for mechanically damaging airway tissue within a human lung, comprising

a flexible elongated inner member having a proximal portion and a distal portion sized to enter a bronchus or a bronchiole of the lung;

a tube-like outer body external to said flexible inner member where said outer body is moveable over at least a portion of said inner member; and

at least one tissue contacting member located at said distal portion of said elongated inner member, said tissue contacting member including a contact area having a hardness sufficient to mechanically damage tissue.

2. The apparatus of claim 1 wherein said tissue contacting members comprise pin-like members extending radially outward from said distal portion, said pin-like members being rigid and substantially inelastic and wherein a portion of said contacting members being radially farthest from said distal portion defines an outer diameter less than an inner diameter of said outer body.

3. The apparatus of claim 1 wherein a portion of said contacting member being radially farthest from said distal portion defines an outer diameter, and wherein said contacting member is moveable such that said outer diameter is variable between a minimum and a maximum diameter.

4. The apparatus of claim 3 wherein each said tissue contacting member comprises a distal elongated blade, a proximal elongated blade and a pivot point joining said blades, wherein said contact area comprises a sharp edge of said blade, said blades being configured to pivot at said pivot point and move said contacting member between said minimum and maximum diameters.

5. The apparatus of claim 4 wherein said distal blade is pivotally connected to a distal end of said elongated inner member and said proximal blade is pivotally connected to said distal end of said elongated outer body, wherein movement of said inner member relative to said outer body causes said blade assembly to pivot at said pivot point.

6. The apparatus of claim 3 wherein said contacting members are resilient, wherein when said contacting members are within said outer body said contacting members are diametrically restrained and wherein advancement of said contacting members out of said outer body allows said contacting members to assume said maximum diameter.

7. The apparatus of claim 6 wherein said contacting members comprise flexible pin-like members extending radially outward from said distal portion and said contact area comprises a distal end of said pin-shaped members.

8. The apparatus of claim 6 wherein said contacting member comprises elongated blades, wherein when said distal portion is advanced out of said outer body said elongated blades extend distally and radially outward from said distal portion.

9. The apparatus of claim 8 wherein said contact area comprises a razor edge.

10. The apparatus of claim 8 wherein said elongated blades comprise rods and said contact area comprises a serrated surface of said rod.

11. The apparatus of claim 8 wherein said elongated blades are spring biased to expand radially outward.

12. The apparatus of claim 1 wherein said tissue contacting members are rotatable about said distal portion.

13. The apparatus of claim 1 wherein said contact area is sharp.

14. The apparatus of claim 1 wherein said contact area is blunt.

15. The apparatus of claim 1 wherein said at least one tissue contacting member comprises a plurality of tissue contacting members.

16. The apparatus of claim 15 wherein said plurality of tissue contacting members are spaced evenly about said inner member.

17. The apparatus of claim 15 wherein said plurality of tissue contacting members comprises four tissue contacting members.

18. The apparatus of claim 15 wherein said plurality of tissue contacting members comprises six tissue contacting members.

19. The apparatus of claim 15 wherein said plurality of tissue contacting members comprises eight tissue contacting members.

20. The apparatus of claim 1 further comprising an expandable member attached to said distal portion of said elongated inner member, wherein said tissue contacting members are attached to a surface of said expandable member, said tube-like outer body further comprising at least one opening corresponding to each of said expandable members, wherein upon expansion of said expandable member said contact area is extended radially away from said distal portion and through said openings in said outer body.

21. An apparatus for damaging airway tissue within a human lung with a fluid or gas, comprising

a flexible elongated inner member having a proximal portion and a distal portion sized to enter a bronchus or a bronchiole of the lung, said elongated member having at least one lumen extending between said proximal and distal portions;

a balloon member located at said distal portion of said elongated inner member, said balloon member being radially expandable, said balloon member having an interior being in fluid communication with at least one of said lumens; and

at least one fluid delivery port located on said exterior of said balloon member.

22. The apparatus of claim 21 wherein said balloon member is radially expandable so that an exterior of said balloon contacts an airway wall.

23. The apparatus of claim 21 wherein said fluid delivery port comprises a plurality of openings on an exterior of said balloon member, said plurality of openings in fluid communication with said interior of said balloon member.

24. The apparatus of claim 21 wherein said fluid delivery ports comprise a plurality of tubes attached to an exterior of said balloon wherein each tube has at least one opening.

25. The apparatus of claim 24 wherein said plurality of tubes are longitudinally along said balloon, said tubes being radially moveable on said balloon exterior.

26. The apparatus of claim 24 wherein said at least one lumen comprises at a first and at least one additional lumen each being discrete, wherein said balloon interior is in fluid communication with said first lumen and said plurality of tubes are in fluid communication with at least one of said additional lumens.

27. A method of increasing gas exchange performed by a lung comprising the step of:

inserting an apparatus configured to mechanically damage lung tissue into an airway of a lung; and

mechanically damaging lung tissue with the apparatus to increase the gas exchange performed by the lung.

28. The method of claim 27, wherein said damaging step includes damaging the lung tissue to cause fibrosis of lung tissue.

29. The method of claim 28, wherein causing fibrosis of lung tissue stiffens the airway.

30. The method of claim 27, wherein the damaging step includes damaging smooth muscle of the airway.

31. The method of claim 30, wherein damaging smooth muscle includes damaging smooth muscle tone of the airway.

32. The method of claim 27 wherein said damaging step includes damaging lung tissue to increase thickness of a wall of the airway.

33. The method of claim 27 wherein said damaging step includes tearing at least a portion of the lung to damage the lung tissue.

34. The method of claim 27 wherein said damaging step includes cutting at least a portion of the lung to damage the lung tissue.

35. The method of claim 27 wherein said damaging step includes damaging said lung tissue in the airway to produce at least one pattern selected from the group consisting of longitudinal stripe, circumferential band, helical strip, a spot, and a combination thereof.

36. The method of claim 35 wherein said spot pattern has a shape selected from the group consisting of rectangular, elliptical, circular, or other shape.

37. A method of increasing gas exchange performed by the lung, comprising:

inserting an apparatus into an airway of a lung; and

damaging tissue with the apparatus where the apparatus is configured to damage tissue by a step selected from:

delivering a liquid that causes trauma to the tissue;

delivering a gas that causes trauma to the tissue;

and applying ionizing radiation to the tissue.

FIG. 1

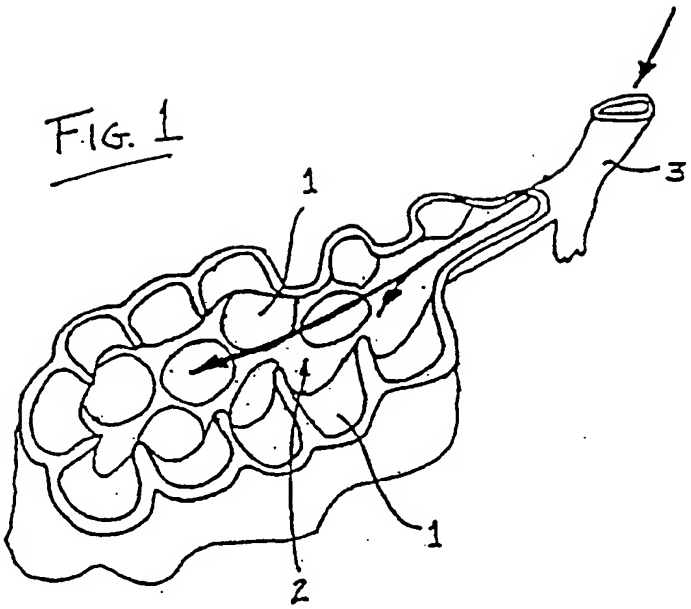
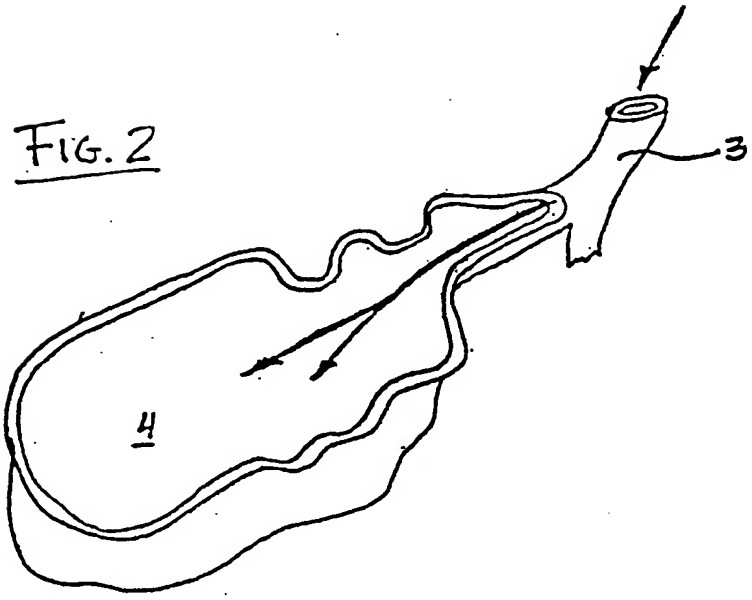


FIG. 2



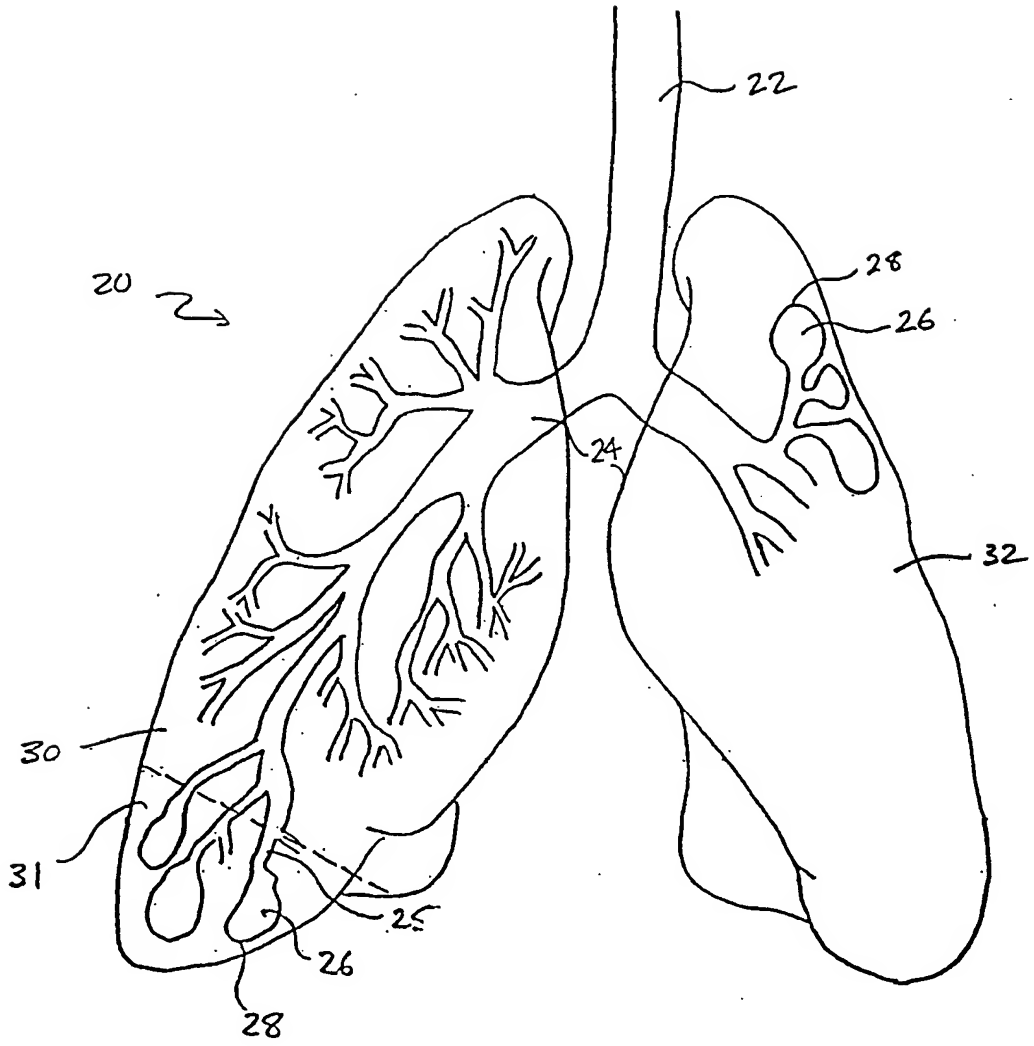


FIG. 3

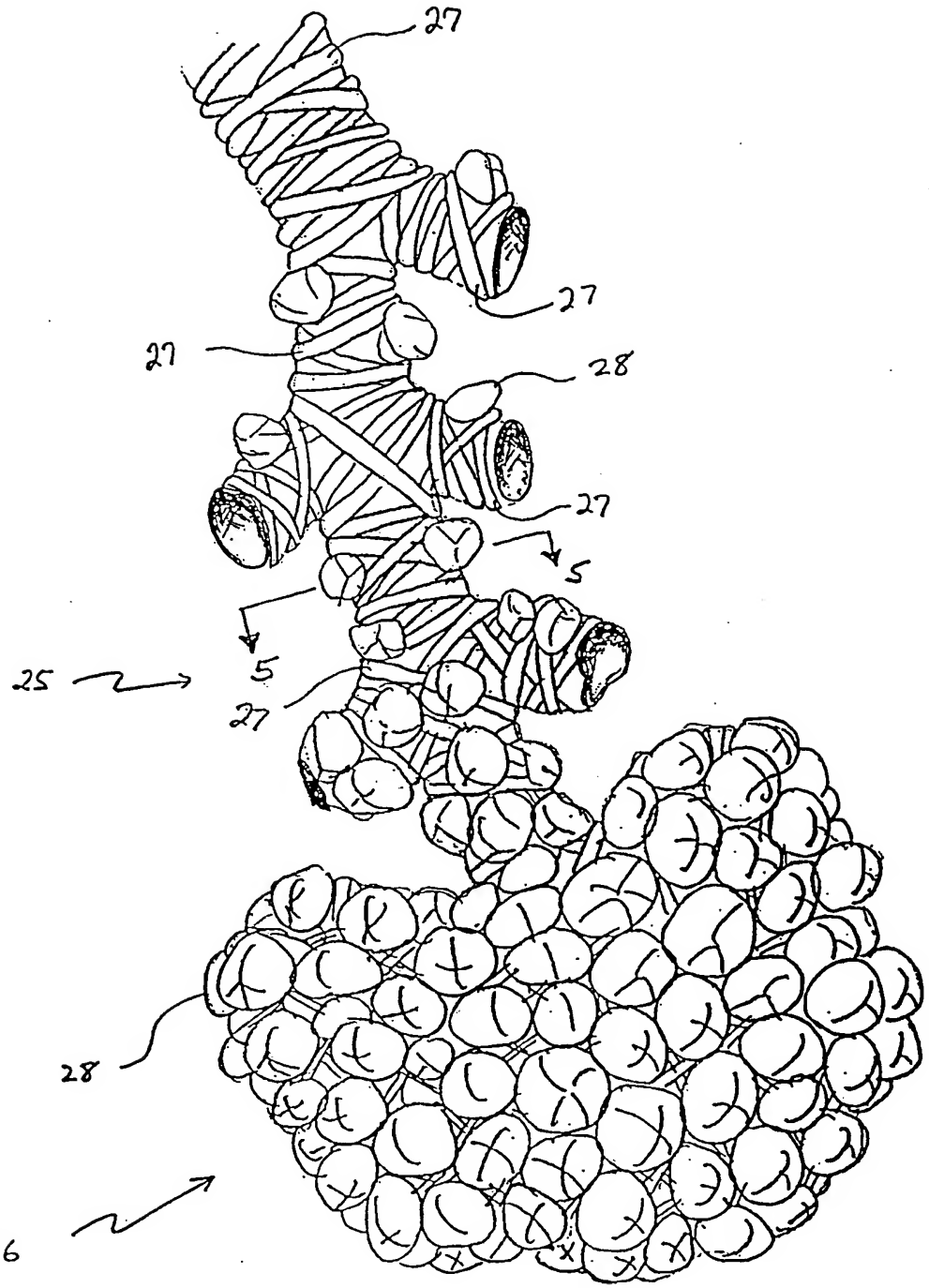


FIG. 4

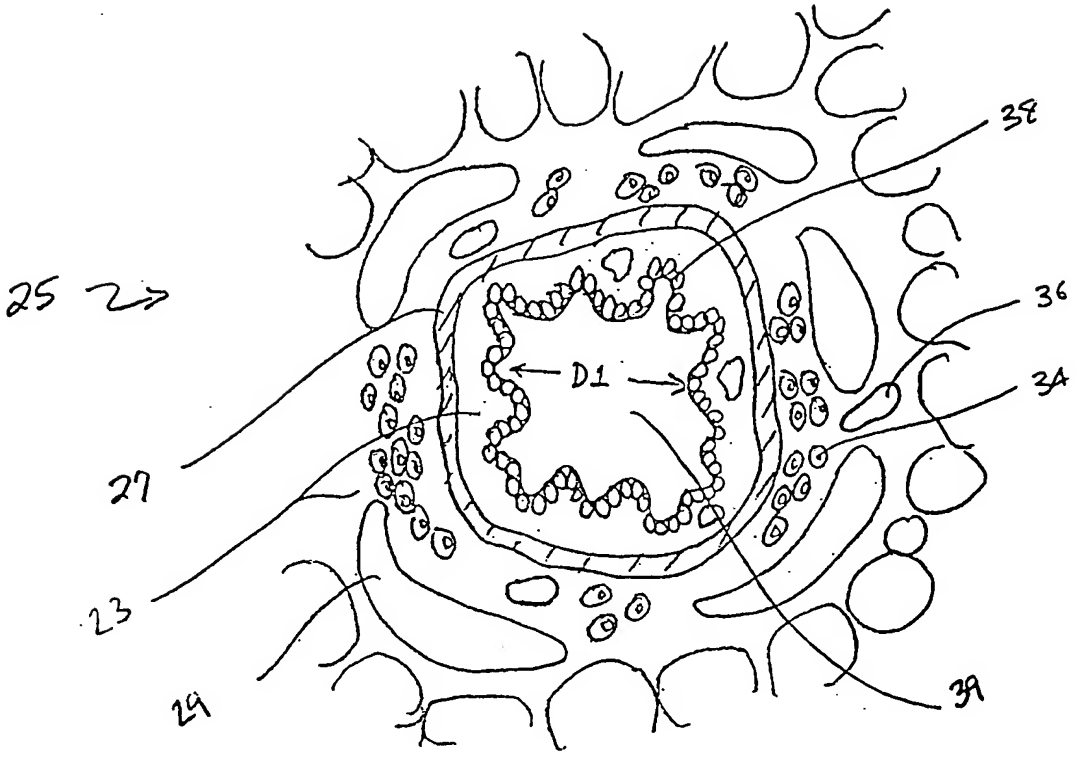


FIG. 5

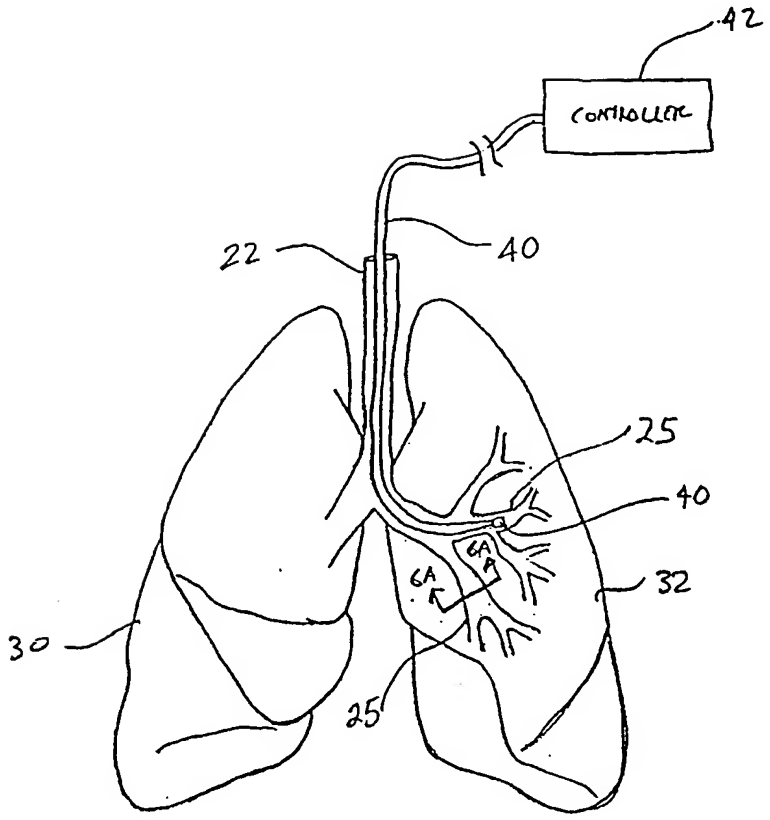


FIG. 6

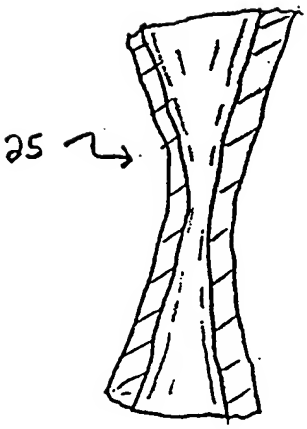


FIG. 6A

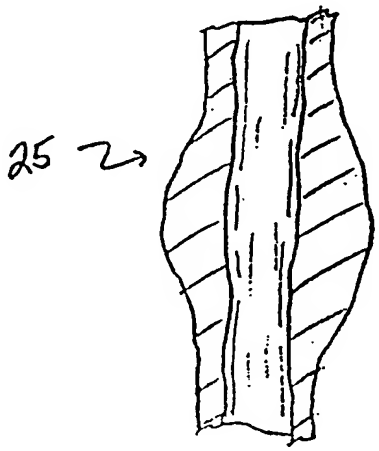


FIG. 6B

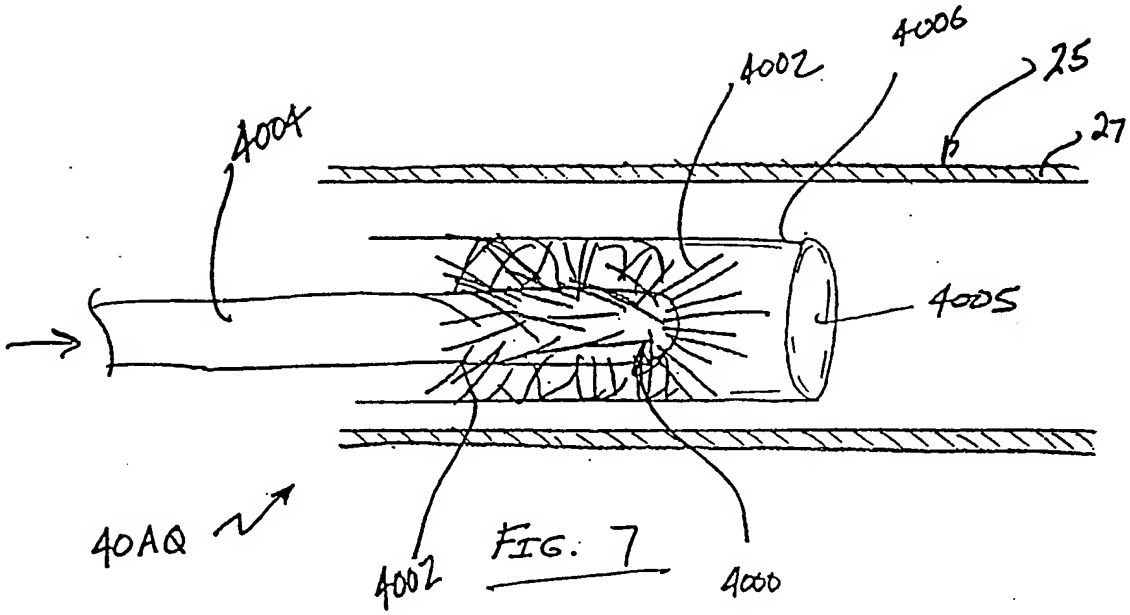


FIG. 7

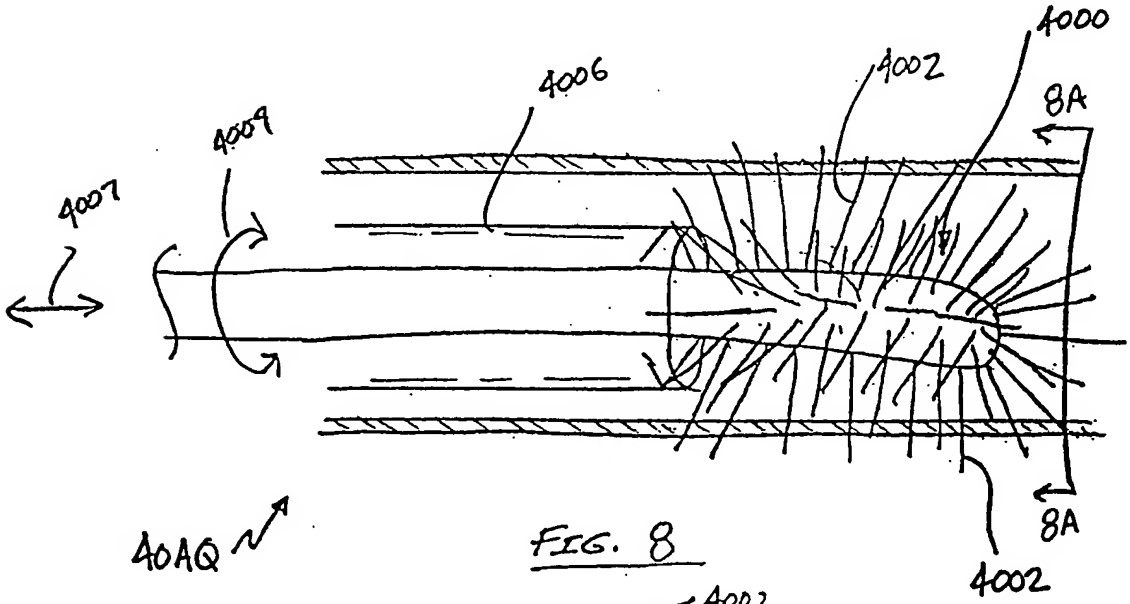


FIG. 8

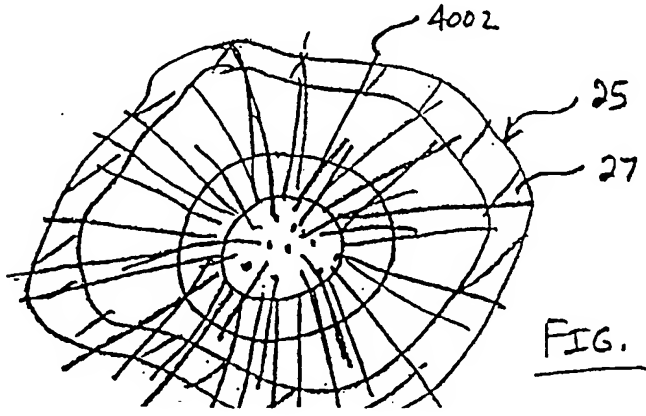


FIG. 8A

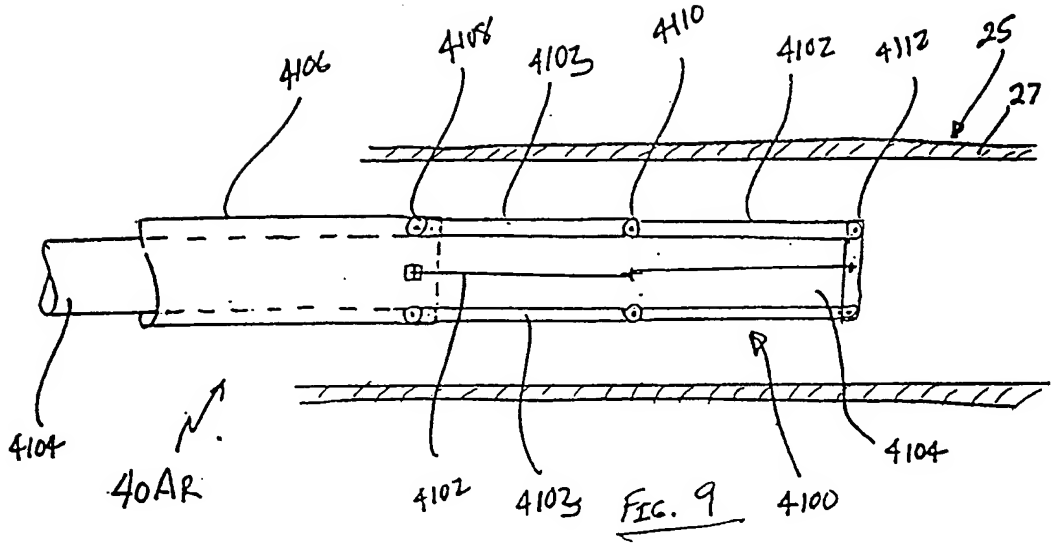


FIG. 9

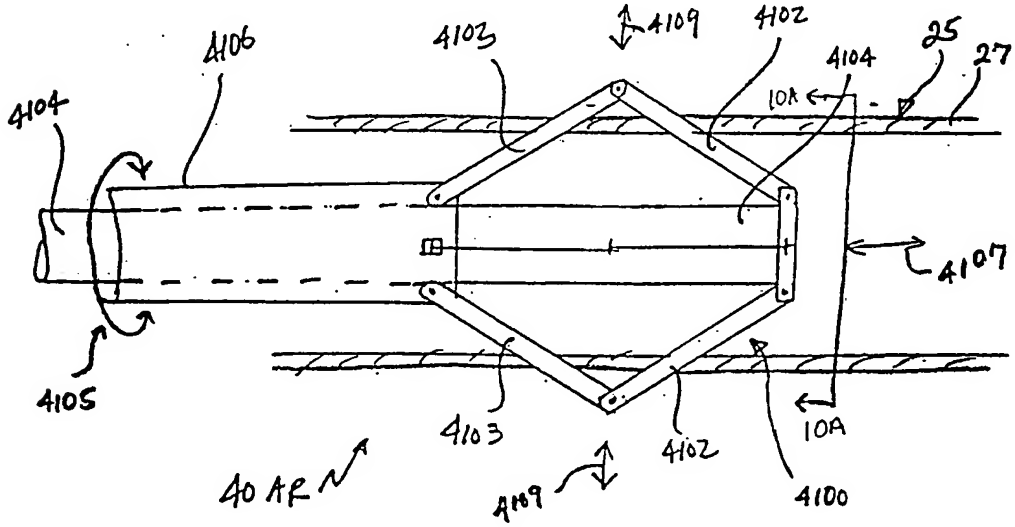


FIG. 10

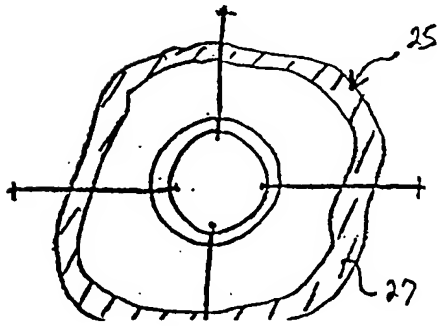


FIG. 10A

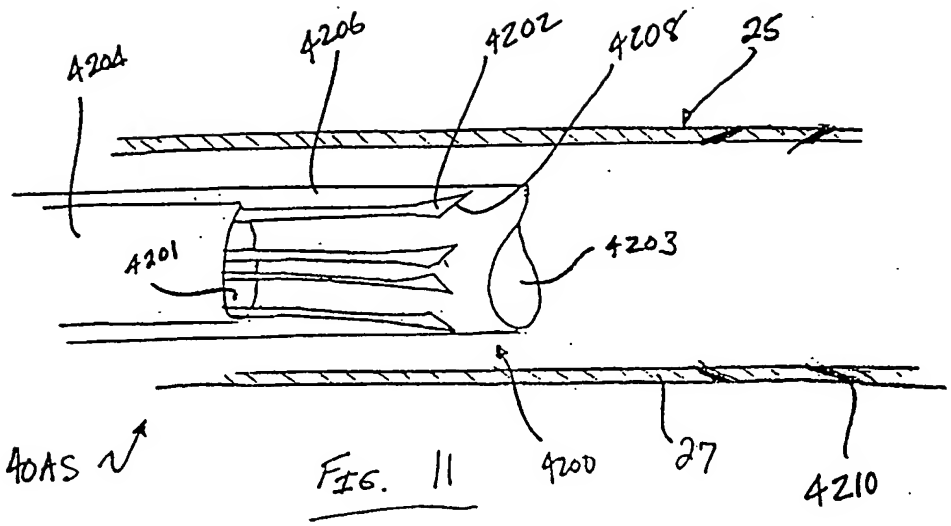


FIG. 11

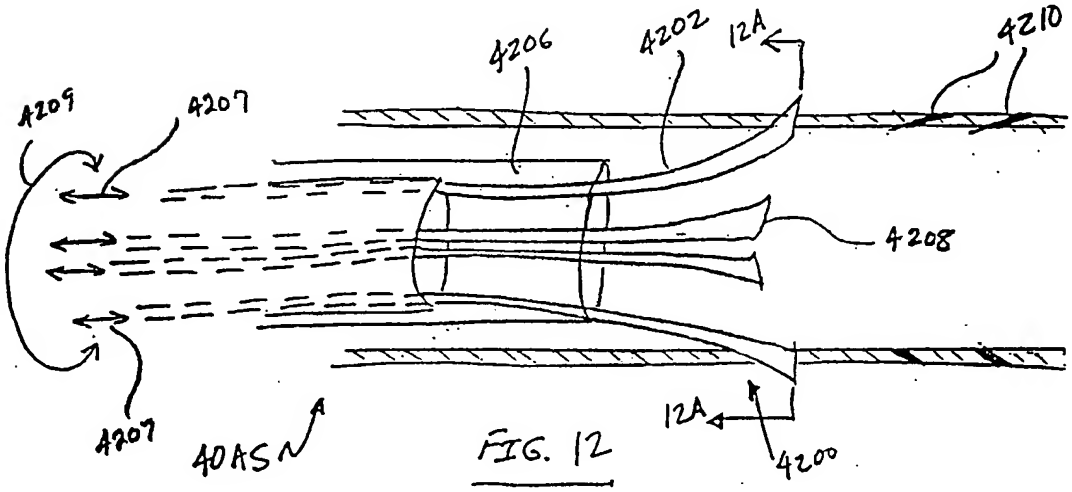


FIG. 12

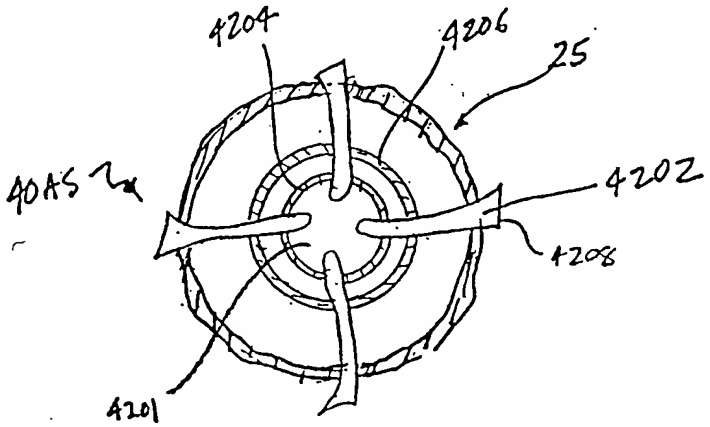


FIG. 12A

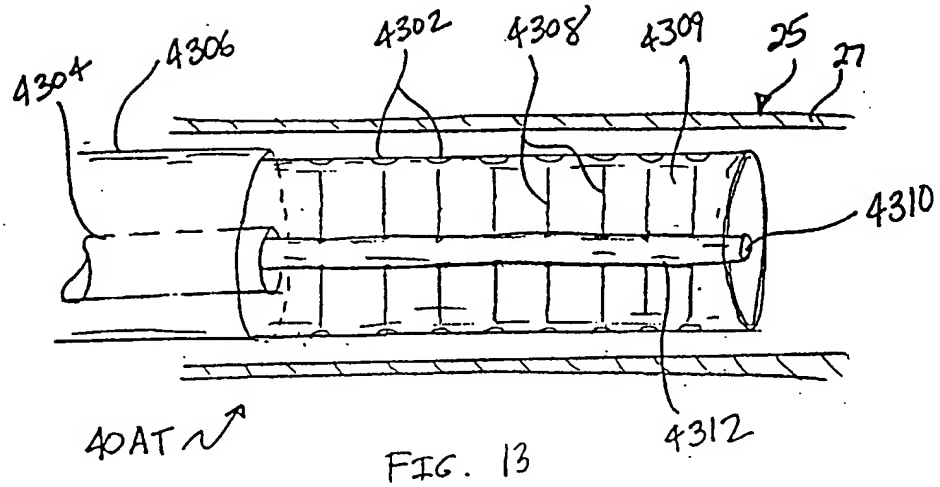


FIG. 13

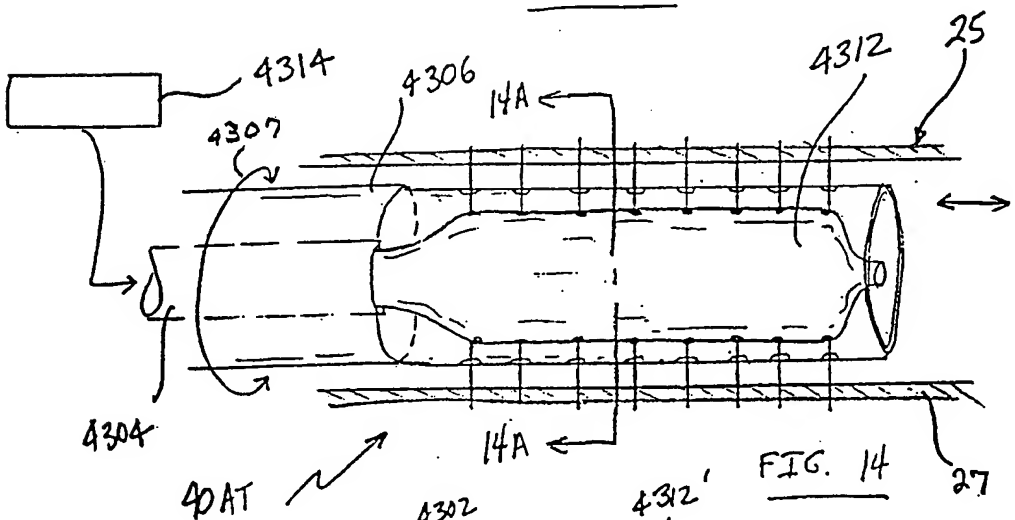


FIG. 14

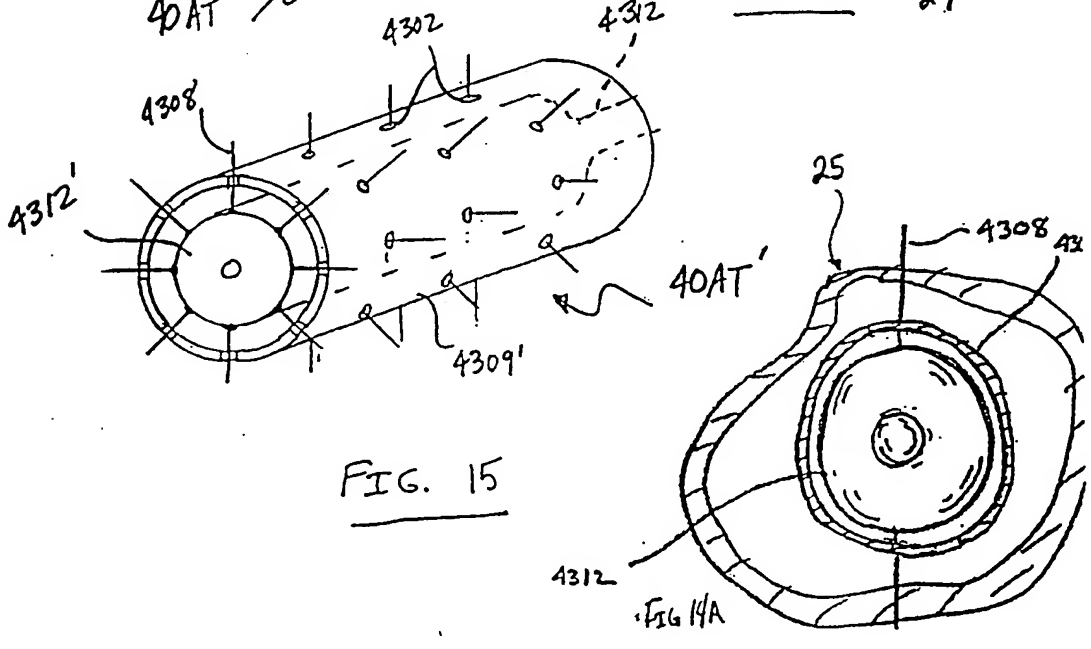


FIG. 15

FIG 14A

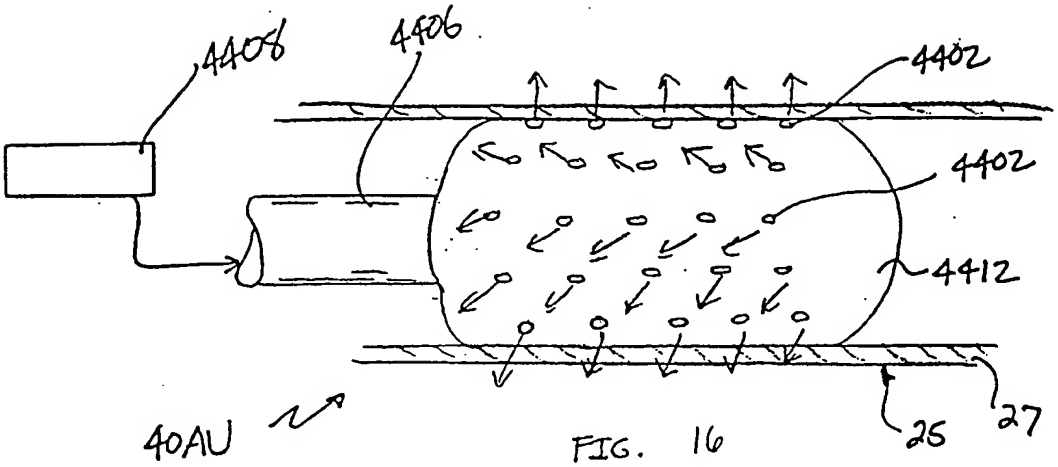


FIG. 16

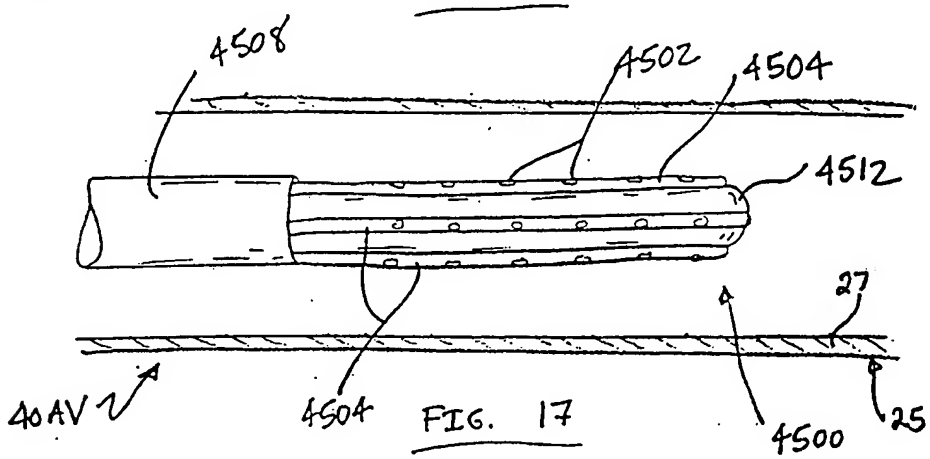


FIG. 17

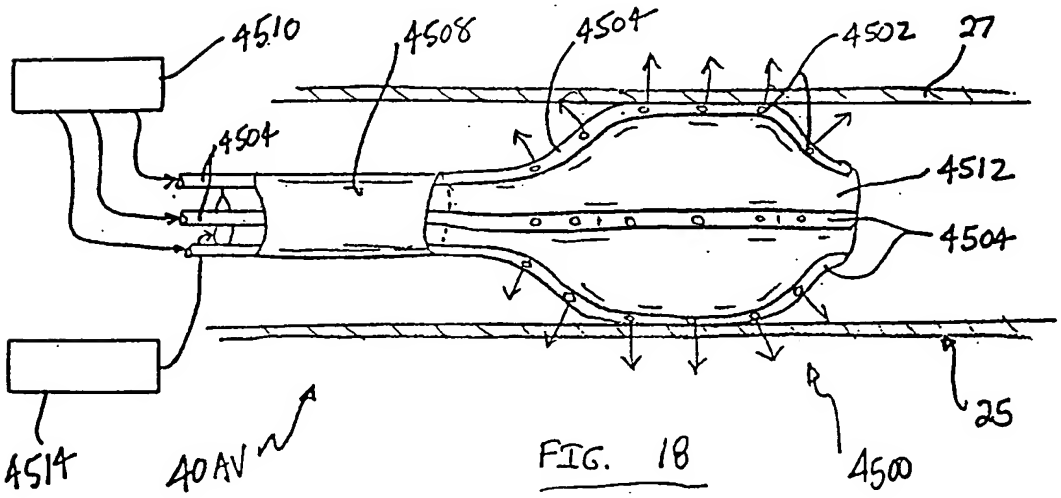


FIG. 18

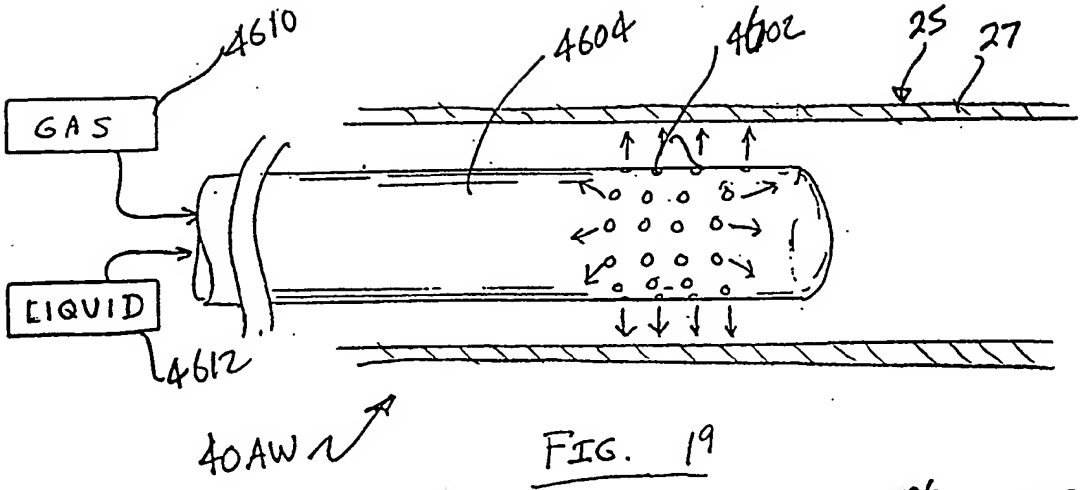

4610
GAS
LIQUID
4612
4604
4602
25
27
40AW

FIG. 19

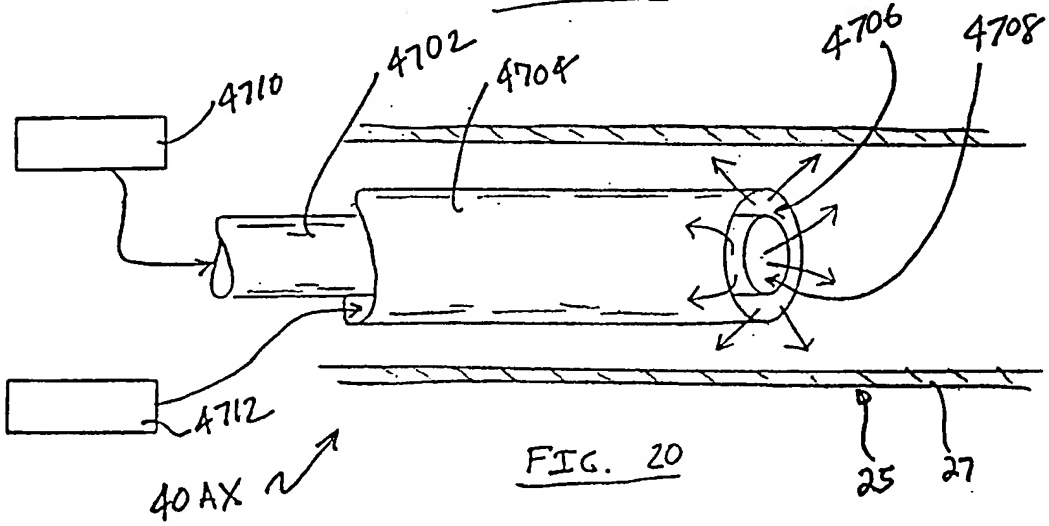

4710
4712
4702
4704
4706
4708
25
27
40AX

FIG. 20

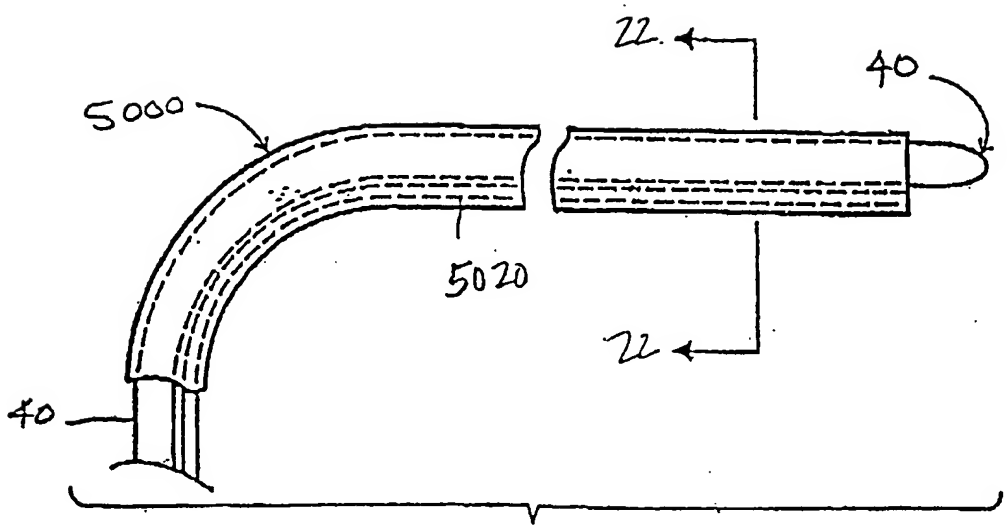


FIG. 21

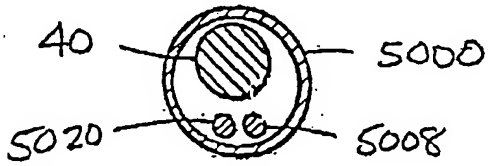


FIG. 22

INTERNATIONAL SEARCH REPORT

Inter onal application No.
PCT/US00/18197

A. CLASSIFICATION OF SUBJECT MATTER
IPC(7) :A61J 7/00
US CL :604/77
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 128/203.12, 204.23, 898, 912, 913, 205.18, 205.19, 207.15; 604/77, 101.02, 102.02, 103.01, 192, 228, 516, 913

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 5,820,554 A (DAVIS et al.) 13 October 1998, entire reference.	1-20
A	US 5,919,172 A (GOLBA, JR.) 06 July 1999 Fig. 1	1-20
Y	US 4,584,998 A (McGRAIL) 29 April 1986, entire reference.	1-20, 27-37
Y	US 5,400,778 A (JONSON et al.) 28 March 1995, entire reference.	27-37
Y	US 5,213,576 A (ABIUSO et al.) 25 May 1993, Figs. 1, 4 & 8.	1, 21-26
Y	US 5,232,444 A (JUST et al.) 03 August 1993, Figs. 1 and 2.	1, 21-26

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

*	Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A"	document defining the general state of the art which is not considered to be of particular relevance	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E"	earlier document published on or after the international filing date	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&"	document member of the same patent family
"O"	document referring to an oral disclosure, use, exhibition or other means		
"P"	document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search 04 SEPTEMBER 2000	Date of mailing of the international search report 03 OCT 2000
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer A. T. NGUYEN Telephone No. (703) 308-2154

Form PCT/ISA/210 (second sheet) (July 1998) *